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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/810,276

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Michael D. Laufer

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EXAMINER

SHAY, DAVID M

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/810,276	Applicant(s) LAUFER, MICHAEL D.	
	Examiner david shay	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 5, 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-11 and 13-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-11 and 13-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>August 5, 2008</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicant has submitted a Declaration, the general points of which were orally presented to the examiner at the interview of June 25, 2008, which was executed by Dr. Michael Laufer (hereinafter the Laufer Declaration) approximately one month subsequent the interview and drawn to the knowledge of one of ordinary skill in the art at the time of the invention with respect to the motivation for combination that the examiner has employed in the rejection under 35 U.S.C. 103(a) applied to the claims in the previous office action. Thus, the Laufer Declaration is not per se drawn to the claimed invention (as it only discusses a subset of the claimed invention wherein all smooth muscle cells are actually killed (see the Laufer Declaration at paragraph 8, last sentence). In the Laufer Declaration Declarant states his educational background; licenses and certifications; and academic positions. In paragraph 4 Declarant establishes that he is not a disinterested third party, having founded the company to which the instant application is assigned, serving on the Board of Directors thereof; being a paid consultant thereof; and holding financial interest therein. In paragraph 5 Declarant sets forth the qualifications of one of ordinary skill in the art. In paragraph 6, Declarant asserts familiarity with the applied art and also the reference to Ivanyuta et al, which was identified by the examiner during the June 25, 2008 interview as a significant piece of prior art with respect to the instant claims. In Paragraph 7, Declarant discusses the teachings of the article to James et al, noting that the submucosa and epithelium, as well as the airway smooth muscle, produce the narrowing of the airway in asthma. Declarant also notes that James et al conclude that changes produced by “chronic inflammatory processes” lead to excessive airway narrowing, citing the first column on page 246 of James et al. The examiner notes that the first column on page 246 of James et al discusses the “chronic inflammatory processes” as including “hypertrophy of smooth muscle...”.

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In paragraph 8, Declarant states that before the present invention, one of ordinary skill in the art would have believed that airway smooth muscle “was of the utmost importance” and served at least one functional purpose. At the end of paragraph 8, Declarant concludes that on the basis of the foregoing, one of ordinary skill in the art would have understood that “airway smooth muscle should not be killed”. In paragraph 9, Declarant refers to a portion of a letter from the FDA denying approval for the treatment of human asthma patients, apparently with the “Asthmatix Alair System”, citing an inability to effectively cough due to lack of smooth airway muscle tone. In paragraph 10, Declarant makes the assertion that “James does not teach or otherwise suggest debulking or reducing the mass of the airway smooth muscle to reverse inflammatory changes for treating asthma.” based on the facts set forth on paragraphs 8 and 9. In paragraph 11, Declarant asserts that one of ordinary skill in the art would understand the call by James et al to reverse inflammatory changes would only be for the inflammatory changes in the epithelium and submucosa and not debulking the airway smooth muscle, due to the knowledge of one of ordinary skill in the art at the time of the invention as set forth in paragraph 8 of the Laufer Declaration; “debulking does not provide acute relief”; and “pharmaceutical treatment of the epithelium may provide acute relief”. In paragraph 12, Declarant analyses the teachings of Regunathan et al. In paragraph 13, Declarant analyses the teachings of the Clarke et al reference. In paragraph 14, Declarant discusses the teachings of Waksman et al noting that the bulk of the Waksman et al disclosure is directed to remedying hyperplasia in injured arteries, Declarant notes that Waksman et al include bronchi and lungs among the lumens to which the device thereof can be applied, but argues “in all of the applications, Waksman’s invention is directed toward treating an area that has been damaged by an earlier procedure” and lastly notes that

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Waksman, moreover, does not disclose anything with respect to causing a change in mucus gland cells". In paragraph 15, Declarant asserts that one "of ordinary skill in the art would have understood that the purpose of both (sic, all of) Regunathan, Clarke and Waksman was to inhibit injured vascular smooth muscle cells from producing additional smooth cells" to prevent hyperplasia". In paragraph 16, Declarant asserts that to one of ordinary skill in the art, "neither Regunathan nor Clarke nor Waksman teaches debulking or otherwise removing uninjured vascular smooth muscle tissue before the injury occurred" noting that none of the references would suggest debulking vascular smooth muscle tissue because "vascular smooth muscle tissue provides an essential function". In paragraph 17, Declarant states that the instant application was filed on June 10, 1998, however, it is noted that it was the parent to the instant application that was filed on this date. Declarant further notes that in the instant method an airway with hypertrophied airway smooth muscle is irradiated with light having a wavelength of about 240 nm to about 280 nm "at an intensity that causes a change in the airway such that the thickness of the airway smooth muscle is reduced (this is instant claim 1) and further notes that another embodiment of the invention includes irradiating an airway with a wavelength of about 240 nm to about 280 nm and an intensity such which causes a change in the airway mucus glands cells such that mucus secretions of the airway are reduced (this is instant claim 10). In paragraph 18, Declarant states that the increase in airway smooth muscle is caused by hypertrophy, not hyperplasia, and thus the method of Clarke, which treats hyperplasia would be inapplicable thereto. In paragraph 19, Declarant asserts that one of ordinary skill in the art would not perform the claimed method based on teachings of the applied references, basically due to the assertions set forth in paragraph 16. In paragraph 20, Declarant asserts that performing the method of

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Clarke et al in an asthmatic airway “would not result in debulking the airway”, noting that “the epithelium in asthmatic airways has several folds” and that the “relatively low angle” of irradiation of Clarke et al “would result in shadowing of the airway, such that some smooth muscle would not be treated”. In paragraph 21, Declarant further asserts that one of ordinary skill in the art would not be motivated to apply radiation to effect a change in the airway mucus gland cells such that mucus secretions are reduced from any combination of the applied references.

The examiner notes that the interview summary stated that the affidavit would overcome the applied art, however, this was based on the oral presentation of the affidavit, which the examiner understood, was to be drawn to the claimed method, and did not include any attachment related to the FDA letter. The examiner is working from memory of the interview, however, the examiner does not recall being informed of the fiduciary duty to (i.e. Board membership) or the financial stake held by Dr. Laufer in the assignee, although the subject of Dr. Laufer functioning as a consultant to the assignee was mentioned. Further it was at least inferred, if not specifically stated in the oral presentation, that the denial by the FDA was for the claimed method. There is no showing whatsoever as to the particular device, let alone the method of application thereof (the claimed invention), and thus the submitted affidavit falls far short of the facts the examiner was led to believe were going to be unequivocally demonstrated by the instant response. Having reviewed the Laufer Declaration, the examiner will now analyze the statements made therein. Firstly, with regard to paragraph 4, there is a clear showing of a financial interest in and a fiduciary duty to the assignee of the instant application on the part of Declarant. Given this, the examiner notes that it has been held that an affidavit, “while not to be

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lightly disregarded, is seldom acceptable as conclusive of factual matter stated therein, in general such affidavits are accorded the status of expression of opinion by expert in the art...yet, law demands close scrutiny of such affidavits, particularly where affiant is not disinterested party” (see *In re Guild* 98 USPQ 68, 69 (CCPA)). Regarding paragraph 7, the summary set forth is accurate. With respect to paragraph 8, the beliefs evidenced by the referenced literature are noted, however, the conclusion drawn therefrom by Declarant appears overly broad, and would seem to indicate that one of ordinary skill in the art would believe that not even the death of a single airway smooth muscle cell could be tolerated, however, the instant claims are of such breadth that they would read on a procedure where only an extremely small number of cells are killed. Thus, the examiner can find no support for such an assertion. Concerning paragraph 9, Declarant proffers denial of an Investigational device Exemption with regard to “Asthmatix’s Alair System”, however, there is no indication as to how this device operates, or the manner in which it was proposed to be used. Did it apply light of some kind? Was it put forth to the FDA as being used to apply this light “having a wavelength of about 240 nm to about 280 nm and an intensity which causes a change in the airway such that a thickness of the airway smooth muscle decreases and bronchioconstriction of the airway is reduced”? Given the complete lack of context with regard to the method that was proposed to the FDA to be performed with this device as compared to the method which is actually claimed, it is impossible to draw any inference from the FDA denial with respect to the knowledge of one of ordinary skill in the art, with respect to the application of the applied references to the claimed invention. Turning now to paragraph 10, Declarant asserts that “James does not teach or suggest (to one of ordinary skill in the art) debulking or reducing the mass of airway smooth muscle to reverse inflammatory changes for

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treating asthma” (parenthetical comments added) is again providing an assertion of what one of ordinary skill in the art would believe James et al teach, but the rejection does not propose that James et al in isolation teach such a treatment, thus this does not overcome the rejection.

Respecting paragraph 11, while James et al teach that treatment of asthma should focus on reversing inflammatory changes in the airway wall, James et al also teach that “the chronic inflammatory process present in the airway wall in patients with asthma is associated with cellular infiltration, deposition of connective tissue; hypertrophy of smooth muscle, goblet cell metaplasia of the epithelium, and an inflammatory exudate containing mucus in the airway lumen” thus to reverse the chronic inflammatory process, would require reversing smooth muscle cell hypertrophy and the excretion of mucus. With regard to paragraphs 12 and 13, these summarize some of the teachings in the Regunathan et al and Clarke et al. Concerning paragraph 14, here Declarant reports some of the teachings of Waksman et al, but the assertion that “in all applications, Waksman’s invention is directed toward treating an area that has been damaged by an earlier procedure” is not entirely accurate, as Waksman et al specifically teach “it should be noted that the method of the present invention may be carries out before during or after an angioplasty or other artery opening procedure” (see Waksman et al page 7, line 36 to page 8, line 1) and “the treating elements any be used to treat the intraluminal passageway through which they are delivered or may be used to treat a surrounding area of the body located within a maximum radius of the of the intraluminal passageway through which they are delivered.” (see Waksman et al, page 5, lines 8-13), the latter could also be construed to refer to mucus glands in the case of treating the bronchi. As to paragraph 15, the assertion by Declarant that “Hyperplasia in vascular applications is the excessive proliferation of new or additional cells above the level of

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normal cell production, whereas hypertrophy is the increase in tissue size, caused by the filling with connective and scar tissue without necessarily increasing the number of smooth muscle cells above normal levels” this shows that hypertrophy can include hyperplasia, (this conclusion is also borne out by the definition of “hyperplasia” in Stedman’s Medical Dictionary, 26th Edition: “An increase in the number of cells in a tissue or organ, excluding tumor formation, whereby the bulk of the part or organ may be increased. SEE ALSO hypertrophy”) further, the fact that James et al specifically state both the production of connective tissue and smooth muscle cell hypertrophy separately as consequences of the inflammatory process which is to be reversed, would point to the hyperplasia meaning of the term hypertrophy, as used in that context. With regard to paragraph 16, since Waksman et al teach applying treatment to uninjured tissue, which is anticipated to experience hyperplasia at some point in the future, and since James et al clearly are referring to the hyperplasia meaning of the term hypertrophy, as set forth above, Declarant’s opinion that one of ordinary skill in the art would not apply the methods taught by Regunathan et al, Clarke et al and Waksman et al is not persuasive. Paragraph 17 the summary of the methods set forth therein is accurate. As for paragraph 18, the assertion that airway thickness increase in asthma is due to hypertrophy, rather than hyperplasia, is not convincing in view of the teachings of the James et al reference in its entirety, as set forth above. Similarly, the conclusion reached in paragraph 19, also based on the erroneous interpretation of the James et al disclosure, and ignoring the totality of the teachings of Waksman et al does not follow. Turning to paragraph 20, Declarant asserts that the method of Clarke et al, if applied to an asthmatic airway, would be ineffective for debulking, because the “relatively low angle” of Clarke et al would produce shadowing. However, given that the angle produced by the device of

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Clarke et al appears similar to the angle produced by the embodiment of Figure 6 of the originally filed disclosure, it would appear that using the same logic, this embodiment would be inoperative. However, the examiner is at a loss to see how either divergence would produce more shadowing than the other. With regard to affecting mucus gland cells, these would appear to be the logical target of efforts to reverse the component of the inflammatory process involving the “inflammatory exudate containing mucus” discussed by James et al and such mucus cells, as shown in Figure 9 of the originally filed disclosure, are clearly “a surrounding area of the body located within a maximum radius of the of the intraluminal passageway” which is taught to be treated by Waksman et al, as set forth above. Lastly, with regard to paragraph 21, it is unclear on what basis the conclusion that “a person of ordinary skill in the art would not be motivated or otherwise think of applying radiation to effect a change in the airway mucus gland cells such that mucus secretions of the airway are reduced” base on the applied references. The Laufer Declaration discusses only the lack of teaching of injuring smooth muscle cells in the bronchi. No discussion of the desire of preserving mucus glands is even asserted, let alone proven. Thus the simple statement that that one of ordinary skill in the art would not be motivated “or otherwise think of” effecting a change in the mucus gland cells is completely unsupported. Further, the specific indication of the mucus excretions as contributing to the inflammatory process by James et al, in the examiner’s view, clearly would motivate one of ordinary skill in the art to take steps to reduce or prevent these secretions.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim1-3, 5-11, and 13-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The disclosure does not teach how radiation with “a wavelength of about 240 nm to about 280 nm” could be effectively applied to mucus cells, which lie below the smooth muscle cells and which muscle, submucosa and epithelium layers are about 65 microns thick in even the smallest bronchioles (see James et al, page 244, Table 1), while ultraviolet wavelengths are strongly absorbed and extinguished within a few microns (see Blum et al column 4, lines 55-68). Further the treatment would be ineffective due to shadowing, as set forth in paragraph 20 of the Laufer Declaration..

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-11, and 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 10 are indefinite, because the exact range to be encompassed by the term “a wavelength of about 240 nm to about 280 nm” is unclear, since it seems to encompass a wavelength of light “in the red visible range” which is recited in dependent claims 5 and 13. Similarly, it is unclear how claims 6 and 14 further limit the claims from which they depend by

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requiring the light source to be one of “an infrared source, a visible source, and an ultraviolet source, in view of the apparent requirement that the emitted wavelengths be in the ultraviolet range. Claim 8 is indefinite as it is unclear what further step or limitation on an existing step is intended to be implied thereby. Similarly, claim 11 is indefinite as it is unclear what further step or limitation on an existing step is intended to be implied thereby, especially in view of the recitation concerning mucus gland cells in the independent claim.

Claims 1-3, 5-11, and 13-15 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ivanyuta et al.

Ivanyuta et al teach the treatment of the bronchi with 633 nm radiation, which is apparently within the range of “about 240 nm to about 280 nm” as evidenced by claim 5. There is no admonition to avoid the treatment of asthmatics with chronic bronchitis.

Claims 1-3, 5-11, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over James et al in combination with Clarke (US '033), Waksman et al, and Regunathan et al. James et al teach that the mechanisms involved in airway narrowing in asthma include hypertrophy of smooth muscle. Regunathan et al teach that restenosis is a result of hypertrophy of smooth muscle cells. Waksman et al teach the equivalence of irradiation of the intima of bronchi and blood vessels to prevent hyperproliferation. Clarke (US '033) teaches that restenosis can be treated by irradiation of the lumen wall with lasers radiation having wavelengths in the claimed ranges to prevent the replication and growth of smooth muscle cells. It would have been obvious to the artisan of ordinary skill use the method of Clarke (US '033) for treating asthma, since bronchial smooth muscle cells and vascular smooth muscle cells are equivalent, as taught by Waksman et al, and both asthma and restenosis involve hypertrophy of smooth muscle cells,

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as taught by James et al and Regunathan et al, and to move the device while irradiating, since this would allow the treatment longer lesions, thus producing a method such as claimed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 7,027,869. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-77 of U.S. Patent No. 6,634,363. Although

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the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1-3, 5-11, and 13-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,488,673. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-54 of U.S. Patent No. 6,411,852. Although

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the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,299,633. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 6,283,989. Although

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the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,283,988. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,200,333. Although

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the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 and 29-32 of U.S. Patent No. 6,083,255. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1-3, 5-11, and 13-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S.

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Patent Application No. 11/614,919. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 5-11, and 13-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent Application No. 11/612,620. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or

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narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 5-11, and 13-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-25 of U.S. Patent Application No. 11/618,533. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 5-11, and 13-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent Application No. 11/617,512. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application

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anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 5-11, and 13-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent Application No. 11/609,242. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent Application No. 11/608,606. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent Application No. 11/ 562,925. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require

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elements A, B, C, and D while instant application claims only requires elements A, B, and C.

Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 5-11 and 13-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent Application No. 11/425,345. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claims 1-3, 5-11, and 13-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent Application No. 11/421,444. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of U.S. Patent Application No. 11/398,353. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant

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application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-50 of U.S. Patent Application No. 11/408,668. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-20 of U.S. Patent

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Application No. 11/420,442. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26 and 27 of U.S. Patent Application No. 11/361,564. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower

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invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 41-46, 48 and 49 of U.S. Patent Application No. 11/117,905. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 5-11, and 13-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29, 30, 32-35, 37, 50, and 52-59 of U.S. Patent Application No. 09/095,323. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the

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copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 5-11 and 13-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 7,264,002. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant

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may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1-3, 5-11 and 13-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 7,273,055. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,273,907. It would have been obvious to the artisan of ordinary skill to use the device for its intended purpose.

Claims 1 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,972,026. It would have been obvious to the artisan of ordinary skill to use the device for its intended purpose.

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Claims 1 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-28 of copending Application No. 11/617,512. It would have been obvious to the artisan of ordinary skill to use the device for its intended purpose.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-17 of copending Application No. 11/612,620. It would have been obvious to the artisan of ordinary skill to use the device for its intended purpose.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 5-11 and 13-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 11/562,910. It would have been obvious to the artisan of ordinary skill to use the device for its intended purpose.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 81-100 of copending Application No. 11/614,914. It would have been obvious to the artisan of ordinary skill to use the device for its intended purpose.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 81-101 of copending Application No. 11/534,621. It would have been obvious to the artisan of ordinary skill to use the device for its intended purpose.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 5-11 and 13-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20, 26, and 27 of copending Application No. 11/618,533. It would have been obvious to the artisan of ordinary skill to use the device for its intended purpose.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-36 of copending Application No. 11/608,606. It would have been obvious to the artisan of ordinary skill to use the device for its intended purpose.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 81-100 of copending

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Application No. 11/614,914. It would have been obvious to the artisan of ordinary skill to use the device for its intended purpose.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 5-11 and 13-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 11/562,925. It would have been obvious to the artisan of ordinary skill to use the device for its intended purpose.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 11/361,564. It would have been obvious to the artisan of ordinary skill to locate the treatment site prior to treatment.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,972,026. It would have been obvious to the artisan of ordinary skill to use the device for its intended purpose.

Applicant's arguments with respect to claims 1-3, 4-11, and 13-15 have been considered but are moot in view of the new ground(s) of rejection.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3769